

**Eastside Neurosurgery, PC**

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December 1, 1999

Document Management Branch (HFA-350)  
Food & Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

**RE: Docket No. 97N-484S**

Dear Sirs:

This is in response to proposed FDA Regulation Docket No. 97N-484S that would allow the FDA to regulate some types of allograft as medical devices. I hope that we all recognize that this clearly is a grey area in terms of regulation.

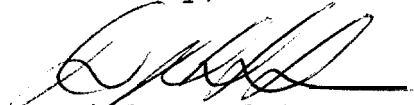
It would strike me that the most efficient use of manpower, and still- provide safety for the patient, is to continue in the current vein whereby allograft bone bank material would be regulated for the safety and the sterility of the processing and the material that is utilized, but that the mechanism or technique in which it is utilized would remain a physician-directed program and not regulated by the Federal Government.

Unfortunately, the technology is changing so rapidly it is difficult to come up with generic rules and regulations that are going to cover these kind of situations. I recognize that some of this bone has been prepared in more than what has normally been thought of as a minimal way; however, it still represents the use of bone allogenic tissue and not a manufactured device.

If the supply of bone products would be significantly curtailed, this would change and alter the practice of medicine in neurosurgical spine management, significantly altering the options available for our patients.

If you have any questions or concerns or should you wish any additional comments, by all means, please feel free to contact me.

Sincerely,

  
Daniel P. Elskens, M.D.

DPE/HSI:mlfm7667.03

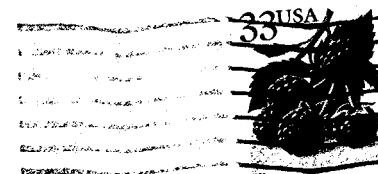
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A Member of St. John Hospital and Medical Center Staff

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